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May 1, 2015

VIA ECF

The Honorable James C. Francis
United States Magistrate Judge
Daniel Patrick Moynihan U.S. Courthouse
500 Pearl Street, Room 18D
New York, New York 10007

Re: *United States ex rel. Kester v. Novartis Pharmaceuticals Corp. et al.*,
Civil Action No. 11-8196 (CM) (JCF)

Dear Judge Francis:

We represent the Relator, David M. Kester, in this case and write to request a pre-motion discovery conference to discuss several discovery issues with Your Honor. These issues relate to Defendant CVS Caremark ("CVS") and the second phase of this case, which concerns the four non-intervened drugs: Gleevec, Tasigna, TOBI, and TOBI Podhaler.

First, to avoid the issues and delay that required the Court to extend the trial schedule in the first phase of this case, Relator asks the Court to set two deadlines: (1) a date by which CVS must substantially complete its production and (2) a date by which CVS must decide whether it will assert a good faith defense to the allegations against it. To date, and despite repeated requests, CVS has refused to commit to a date for either of these items.

Second, Relator asks the Court to order CVS to produce eight categories of documents and other information as basic as the identity of the former CVS customer service representatives who contacted patients about the drugs at issue, communications regarding the referral of patients to CVS, and its bonus policies—all of which plainly are relevant to Relator's claims in this case.

I. Brief Background

The second phase of this case is similar in many respects to the first phase. As Judge McMahon recognized in *Novartis V*, Relator's core allegation is that "[b]eginning in or about January 2007 and continuing through the current time, Novartis management has employed a scheme to increase sales of certain specialty medications by corrupting the medical objectivity of pharmacists who are responsible for counseling patients on the most appropriate medication for their conditions." TAC, Dkt. 253 at ¶ 76; *see Novartis V*, Dkt. 233 at 4-5. Relator alleges that Novartis effectuated this scheme using various "kickbacks . . . to induce [specialty pharmacies] to 'recommend' its drugs to doctors or patients." TAC, Dkt. 253 at ¶ 76. These kickbacks included "valuable rewards—including patient referrals and cash payments styled as 'performance rebates' or 'performance discounts'"—as well as patient referrals. *Id.* at ¶¶ 76, 89.

At a high level, the main difference between the two cases is that Phase 2 involves additional defendants (including CVS) and concerns four different drugs: Gleevec, Tasigna, TOBI, and TOBI Podhaler. In addition, neither the United States nor any state government has intervened. Phase 2 also is on a different schedule. The Court authorized discovery to begin on September 3, 2014. Relator began serving defendants, including CVS, with requests for production and interrogatories one week later. Prior to April 10, 2015, CVS had produced to Relator a total of 42 documents in response to these requests. Since then, CVS has produced an additional 5,231 documents—which Relator expects to finish reviewing by the end of the next week.

Complicating matters, Relator does not know how many additional documents CVS has yet to produce because CVS refuses to disclose how many documents "hit" on its search terms. Relator first requested a hit count after CVS proposed initial search terms in December 2014. Ultimately, after several requests and several meet and confers, Relator agreed to an initial set of search terms in April 2015 without getting a count and before receiving a single CVS document that was not a formal contract, amendment, or contract-related notice. Only after Relator agreed to terms did CVS start producing the non-contractual documents that would allow Relator to make an informed decision regarding terms.

II. Argument

A. Relator Asks the Court to Impose Two Deadlines on CVS.

Relator's first set of requests are intended simply to further the efficient completion of discovery in this case. Under the current schedule, discovery will close August 31, 2015, and Relator's expert reports are due more than a month

prior on July 21, 2015. To meet these deadlines, Relator needs to start deposing witnesses and assembling the documents that support his claims.

To push toward these goals, Relator has asked CVS several times to commit to a specific date by which it will substantially complete its production of materials responsive to Relator's current requests—information that, among other things, would allow Relator to decide when to begin scheduling depositions. *Cf. Halcon Int'l v. Snam Progetti, SPA*, No. 68 CIV. 956, 1968 WL 88499, at *5 (S.D.N.Y. Dec. 27, 1968) (granting request to postpone depositions "until substantial completion of plaintiff's Rule 34 discovery of documents and records" because, "[i]f plaintiff were to take the depositions before the documents were produced for inspection, there would be the risk that it would later discover documents containing new matter which would necessitate further depositions; whereas if it inspects substantially all of the documents before embarking upon the depositions, this risk will be minimized").

For similar reasons, Relator also has asked CVS to commit to a date by which it will tell Relator whether it is going to pursue the good faith defense it pleaded—a decision that will directly affect the scope of discovery in this case. *Compare* CVS Answer, Dkt. 328 at 35 (asserting that "Relator's claims are barred, in whole or in part, because CVS did not act knowingly within the meaning of the False Claims Act."), *with* Dkt. 374, 394 (discussing waiver implications of good faith defense).

Notwithstanding Relator's need for this information to prepare his case, and notwithstanding its telling the Court that "there is no reason to alter the current schedule" because "CVS has been diligently collecting, reviewing, and readying [its documents] for production," Letter, Dkt. 397 at 1-2, CVS has refused to provide Relator with an answer to either question. CVS thus leaves Relator no choice but to ask the Court to require CVS to substantially complete its production and tell Relator whether it intends to pursue a good faith defense by a date certain. *Cf. Patroski v. Ridge*, No. 2:11-CV-1065, 2011 WL 5593738, at *2 (W.D. Pa. Nov. 17, 2011) (agreeing that party should not be forced to "choose between deposing adverse witnesses without complete documents or substantially delaying these depositions"). To allow Relator sufficient time to review documents and take depositions in advance of the July 21 expert report deadline, Relator respectfully asks the Court to require CVS to do both by June 1, 2015.

B. Relator Asks the Court to Order CVS to Respond to Interrogatories and Produce Responsive Documents as Relator Has Requested.

The remainder of this letter concerns discovery issues that the parties have discussed at length but have not been able to resolve. Relator asks the Court to break the parties' impasse by directing CVS to respond to this discovery.

The standard for evaluating CVS's refusals to produce is straightforward. As Your Honor has explained, the party requesting discovery needs to show only that the information sought "is relevant to any party's claim or defense." *US Bank Nat. Ass'n v. PHL Variable Ins. Co.*, 288 F.R.D. 282, 284 (S.D.N.Y. 2012) (Francis, J.) (quoting Fed. R. Civ. P. 26(b)(1)). And "[a]lthough not unlimited, relevance, for the purpose of discovery, is an extremely broad concept"; it "encompass[es] any matter that bears on, or that could lead to other matters that could bear on, any issue that is or may be in the case." *Id.* (second alteration in original) (citation and internal quotation marks omitted). So long as "the discovery appears reasonably calculated to lead to the discovery of admissible evidence," it is relevant and discoverable. *Id.* (quoting Fed. R. Civ. P. 26(b)(1)).

Once relevance has been shown, the burden shifts to the party opposing discovery to "show specifically how, despite the broad and liberal construction afforded the federal discovery rules, each request is not relevant or how each question is overly broad, burdensome or oppressive." *Id.* at 285 (citation and internal quotation marks omitted). "General and conclusory objections as to relevance, overbreadth, or burden are insufficient to exclude discovery of requested information." *Id.* (same).

1. Documents and Information "Relating To Any Time Period Before April 1, 2010"

The first impasse issue is CVS's wholesale refusal to produce documents or disclose information "relating to any time period before April 1, 2010"[1]—the start date for its liability in this case. *E.g.*, Ex. 1 at 5 ¶ 17 ("CVS objects to the Requests to the extent they seek information relating to any time period before April 1, 2010 . . . . In responding to the Requests, CVS will provide information and/or documents from the period April 1, 2010 through January 8, 2014."). CVS's position is improper for at least two reasons.

[1] Notwithstanding its objection, CVS has represented that it produced any contracts, amendments, or notices for the drugs at issue that remained in effect as of April 1, 2010.

First, the fact that the Court applied the public disclosure bar to dismiss Relator's pre-April 1, 2010 claims against CVS does not preclude Relator from obtaining pre-April 1, 2010 discovery from CVS. The public disclosure bar is "not designed as a discovery rule" and does not supplant ordinary discovery principles. *U.S. ex rel. McCartor v. Rolls-Royce Corp.*, No. 1:08-CV-00133-WTL, 2013 WL 5348536, at *4 (S.D. Ind. Sept. 24, 2013) (rejecting argument that discovery in *qui tam* cases is more limited than in ordinary case). And it is understood that a party can obtain discovery regarding actions that occurred before the liability period. *Flomo v. Bridgestone Americas Holding, Inc.*, No. 106-CV-00627-DFH-JMS, 2009 WL 1456736, at *2 (S.D. Ind. May 20, 2009) ("As Plaintiffs correctly point out, courts often find that matters occurring before the liability period satisfy the low 'relevance' standard for discoverability."). The reason is simple. While "acts committed prior to the charge period may not be redressable through damages, they may be relevant evidence in providing background and context to the parties' interactions." *Tzoumis v. Tempel Steel Co.*, No. 96 C 6945, 2001 WL 99697, *2 (N.D. Ill. Feb. 1, 2001).

That is precisely the case here. Undoubtedly, CVS communicated with Novartis prior to April 1, 2010, about the efforts CVS agreed to make to push Novartis's products. Similarly, CVS undoubtedly discussed the remuneration it expected in return. And these are just two specific examples of the broad range of communications and actions that undoubtedly occurred prior to April 1, 2010, that provide background and context for what CVS did after that date. Because such actions bear on CVS's liability, they are relevant and discoverable. *Id.*; *see US Bank*, 288 F.R.D. at 284. On this basis alone, CVS's blanket refusal to produce documents "relating to any time period before April 1, 2010" is improper.

Second, even setting aside the relevance of such documents and information to the conduct of CVS, these materials bears directly on the actions and liability of Novartis, which *is liable* for its pre-April 1, 2010 conduct, including its use of kickbacks to induce CVS to recommend patients order the Novartis specialty medications at issue. TAC, Dkt. 253 ¶ 1; *see Novartis V*, Dkt. 233 at 36. Thus, regardless of the extent of CVS's own liability, its pre-April 1, 2010 materials are independently relevant and should be produced.

For either of these reasons, Relator asks the Court to order CVS to search for and produce documents dating back to January 1, 2007—the same date used by each of the other defendants in this action.

2. The Scope of TOBI Podhaler

The second impasse issue concerns limitations CVS has placed on its production of documents and information related to TOBI Podhaler—one of the four "Covered Drugs" at issue in the second phase of this case.

Arguing that Relator's TOBI Podhaler allegations are limited to claims that it attempted to switch patients from TOBI to TOBI Podhaler, CVS refuses to produce any documents or information that could also relate to TOBI Podhaler patients who did not switch from TOBI to TOBI Podhaler. Thus, for example, CVS will not produce documents and information related to *general* market share goals or refill targets—despite the fact that such general goals and targets would provide an incentive for switching patients. CVS said it would produce only those goals or targets specific to switched patients (if any exist). CVS also refuses to produce information related to competing drug products like compounded tobramycin—despite the fact that such drugs bear directly on the medical and financial justification CVS had for trying to switch patients to TOBI Podhaler. *Cf.* TAC, Dkt. 253 at ¶ 134 (alleging that one of Novartis's goals was to dissuade a pharmacy "from promoting and advocating compounded tobramycin").

No credible justification exists for depriving Relator of this relevant and discoverable information. As demonstrated above, even if Relator's TOBI Podhaler allegations were limited to literal efforts to switch patients from TOBI to TOBI Podhaler, this does not justify the line CVS draws. Programs and directives related to TOBI Podhaler *as a whole* bear on or at least are reasonably calculated to lead to the discovery of evidence that bear on the reasons or incentives that explain why CVS wanted to switch patients from TOBI to TOBI Podhaler. The same is true of documents and information related to competing drug products, especially those that reflect pressure or incentives CVS received to dispense TOBI Podhaler in lieu of those competing products.

Moreover, Relator's TOBI Podhaler allegations actually are *not* limited to switching claims. Relator broadly alleges that "[b]eginning in or about January 2007 and continuing through the current time, Novartis management has employed a scheme to increase sales of certain specialty medications" by offering various "kickbacks . . . to induce [specialty pharmacies] to 'recommend' its drugs to doctors or patients." TAC, Dkt. 253 at ¶ 76. And Relator identified the specialty medications at issue as "Gleevec, Exjade, Tasigna, TOBI, *including TOBI Podhaler*, and Myfortic." *Id.* at ¶ 160 (emphasis added).

In short, Relator identified TOBI Podhaler as one of the drugs involved in the general overarching fraudulent behavior at issue in this case. And in such

cases, discovery is not limited to the specific allegations of wrongdoing identified in the complaint. As one court explained:

> It is unreasonable, in this judge's view, to impose a limit on discovery and recovery in *qui tam* cases to specific examples of fraudulent behavior that relators were able to describe in their complaint when—as in this case—the complaint describes a general fact pattern of alleged fraudulent behavior supported by specific examples of that behavior. The court sees *no good reason* to prevent a relator from discovering *other examples of behavior* substantially similar to those described in the complaint and *that similarly fit the pattern of conduct on which the complaint is focused*.

McCartor, 2013 WL 5348536, at *6 (emphasis added).

For each of these reasons, Relator asks the Court to order CVS to treat TOBI Podhaler as a "Covered Drug" for purposes of responding to his requests and not limit its TOBI Podhaler production to documents or information that concern exclusively those patients who switched from TOBI to TOBI Podhaler.

3. The Identity of Former Customer Service Representatives

Interrogatory 1 asks CVS to "[p]rovide the name, most recent job title, and last known contact information of every current or former Customer Service Representative" it paid to contact patients regarding the Novartis drugs at issue. Prior to yesterday, CVS has not identified a single representative. And though it has now supplemented its response to identify a long list of *current* representatives that work in groups dedicated either to oncology drugs or TOBI,[2] CVS has said it will not make any effort to identify *former* representatives—claiming that doing so would be unduly burdensome. Relator disagrees.

As a threshold matter, CVS cannot disagree that the identities of those former CVS employees who communicated with patients are relevant to Relator's claims. Not only were customer service representatives CVS's boots on the ground—talking directly with patients to convince them to purchase the drugs at issue—but former employees are far more likely to openly and fully discuss their actions, concerns, and motivations than current employees. To avoid disclosure, the burden thus is on CVS to "show specifically how, despite the broad and liberal construction afforded the federal discovery rules, each request is not

[2] CVS also disclosed one "technician" whose "date range" it listed as "unknown."

relevant or how each question is overly broad, burdensome or oppressive." *US Bank*, 288 F.R.D. at 284. It cannot make this showing here.

Even in the abstract, it would be extremely unlikely that CVS cannot identify its own former employees who it paid to call patients to discuss the drugs at issue using the *drug-specific scripts* Novartis required it use—especially given that calls were required to be made to *specific* patients on *drug-specific* intervals. *See* TAC, Dkt. 253 at ¶ 92. In short, the entire structure of the system necessitated that CVS know which employees were calling which patients about which drugs. And if that alone was not enough, CVS's contracts with Novartis also specifically require that "[redacted]" Ex. 2 at 21. They also require CVS "[redacted]" with its Gleevec, Tasigna, TOBI, and TOBI Podhaler Agreements to, among other things, "[redacted]" and "[redacted]" *E.g.*, Ex. 3 at 4 ¶ 3.3.

Given these facts, it is simply implausible that CVS has no way to identify the employees at issue. Relator asks the Court to order CVS to do so immediately.

4. Documents Concerning Referrals of Patients to CVS (RFP 13)

The next category of documents CVS refuses to produce are those that relate to the referral of patients to CVS by Novartis and/or a Hub. Specifically, despite the fact that Relator requests "all Documents concerning referrals of Patients to Defendant, including but not limited to Communications with Novartis or a Hub," CVS has told Relator it will produce only those reports CVS received from a Hub that contained actual patient referrals—nothing more.

No credible basis exists for this limitation either. As Judge McMahon recognized in *Novartis V*, one of Relator's core allegations is that Novartis used "patient referrals" to induce "Caremark and other specialty pharmacies" to participate in its kickback scheme. Dkt. 233 at 5 (relying on Relator's allegation that Novartis "offered them [specialty pharmacies] kickbacks in the form of rebates, discounts, *and patient referrals*" (emphasis added)); TAC, Dkt. 253 at ¶ 76. In and of itself, this shows that referral-related documents *other* than the actual instrument used to refer a patient to CVS are relevant and discoverable. This

[3] Pursuant to the terms of the Protective Order entered in this matter, Relator has redacted any Confidential Information from this filing and has delivered to the Court in a sealed envelope an unredacted copy of this letter and any confidential documents he cited. Dkt. 232 at ¶ 23; Dkt. 385-1. Relator also will provide a copy of each of these documents to each party.

includes, for example, emails between CVS and Novartis related to the number of referrals CVS received or would receive, how those numbers were determined, or the steps CVS could take to increase the patients referred to it. All of these documents bear on the scheme as a whole; thus all are relevant and discoverable.

Moreover, as Relator alleges in his complaint, Novartis used referrals not just as a carrot, but as a stick—penalizing "lagging pharmacies[] by sending more patients to the higher performing pharmacies." TAC, Dkt. 253 at ¶ 89. Permitting CVS to limit its production to just the reports used to refer patients would preclude Relator from discovering additional evidence to support this key point.

5. Communications Related to a Covered Drug Performance Benefit Contract or Covered Drug Discount (RFP 42 & 43)

The parties' dispute as to these requests concerns the term "Covered Drug Discount," which Relator defined to mean any "rebate, discount, credit, chargeback, adjustments, or other remuneration" CVS received for dispensing a Covered Drug. Notwithstanding this definition, CVS refuses to produce documents in response to this request that do not relate to remuneration labeled literally as either a "rebate" or "discount"—arguing that Relator's allegations are limited strictly to those two specific forms of remuneration. Not only is this not true, but it would be irrelevant in any case.

Relator's core allegation is that Novartis "employed a scheme to increase sales of certain specialty medications . . . by paying Accredo, Bioscrip, Curascript, and Caremark and other specialty pharmacies *valuable rewards*—*including* patient referrals and cash payments styled as 'performance rebates' or 'performance discounts.'" TAC, Dkt. 253 at ¶ 89 (emphasis added). At no point did Relator limit his allegations to rebates and discounts. Those simply are two *examples* of the "valuable rewards" or kickbacks CVS received.

Moreover, even if Relator had alleged only that CVS received "discounts" and "rebates," that would not preclude him from obtaining discovery regarding other forms of kickbacks. As explained, the scope of discovery in a *qui tam* case is not limited to the "specific examples of fraudulent behavior that relators were able to describe in their complaint." *McCartor*, 2013 WL 5348536, at *6. At a minimum, a relator is entitled to obtain discovery related to other behavior "that similarly fit the pattern of conduct on which the complaint is focused." *Id.* Here, that pattern of conduct plainly includes payments or remuneration CVS received other those explicitly labeled as "discounts" or "rebates."

And to be clear, this is not an issue of semantics or baseless concern. Rather, Relator is aware that, [redacted]

[redacted][4] Ex. 4 at 1 ¶ 2. And despite the fact that these fees clearly are a "valuable reward" Novartis used to get CVS to increase its sales of Novartis specialty medications, they are not labeled either as a "discount" or "rebate." Relator therefore will not be able to obtain discovery regarding this remuneration if CVS's objection is permitted to stand.

6. Advertisements for Employment Applications (RFP 11)

Request No. 11 asks CVS to produce its advertisements for employment applications for Customer Service Representatives, which Relator defined to mean any employee "whose job responsibilities include communications with Patients or with Health Care Providers relating to a Covered Drug." CVS refuses to produce these documents, claiming they are irrelevant and overly burdensome to produce. Neither is true.

First, through its own actions, CVS has put these documents at issue. Relator anticipates—and CVS does not deny—that it will defend its conduct at trial in part by arguing that defendants created and implemented the schemes at issue in an effort to improve patient care—not just to boost their bottom lines. In short, they intend to put their motivations at issue, which entitles Relator to discovery that bears on that motivation. This includes the advertisements CVS used to hire the very employees that called patients to encourage them to order the Novartis drugs at issue. For example, if those advertisements solicit applicants with prior sales experience (as opposed to prior medical or counseling experience) or emphasize the commissions or bonuses applicants would be eligible to receive based on the number of drugs sold, that is strong evidence that CVS's motivation (and the motivation of its employees) was not as altruistic as it claims. *See In re Vivendi Universal, S.A.*, 381 F. Supp. 2d 158, 185 (S.D.N.Y. 2003) (holding that evidence that employee would receive "a concrete and personal benefit in the form of a bonus" from a transaction was relevant to establishing "an intent to deceive, manipulate, or defraud" (citation and internal quotation marks omitted)).

Second, despite repeated requests, CVS has yet to provide any evidence to support the undue burden it claims. The most it even has claimed is that, because it did not store its advertisements at a central location, complying with Relator's request would require it to obtain documents from its various specialty pharmacy locations. That is not enough. "The fact that a responding party maintains records in different locations . . . does not suffice to sustain a claim of undue burden."

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[4] Novartis also used terms like "performance benefits" to describe the remuneration it gave to specialty pharmacies that distributed Myfortic—one of the Phase 1 drugs.

Thomas v. Cate, 715 F. Supp. 2d 1012, 1033 (E.D. Cal. 2010) (quoting *Greystone Constr., Inc. v. Nat'l Fire & Marine Ins. Co.*, No. CIVA07CV-00066MSKCBS, 2008 WL 795815 *6 (D. Col. 2008) (citing cases)).

Moreover, Relator notes that, notwithstanding the legal insufficiency of the burden CVS claims, Relator tried to address that alleged burden. As a courtesy to CVS (and subject to the caveats noted below),[5] Relator offered to allow CVS to produce advertisements from just a handful of its locations, which Relator could then review in order to make an informed decision as to whether advertisements from other locations were necessary. CVS rejected that offer.

7. Bonus Policies (RFP 60)

For much the same reason as those stated above, Relator asks the Court to order CVS to produce documents or materials that relate to its bonus or "Incentive Compensation Practices for any Employee whose work concerned a Covered Drug." These materials likewise bear directly on the motivation CVS and its employees had for calling patients to encourage them to order the Novartis drugs at issue. *Vivendi*, 381 F. Supp. 2d at 185.

8. Material CVS Intends to Use or May Use to Impeach (RFP 40)

Finally, Relator asks the Court to order CVS to produce any documents or materials it intends "to use or may use for impeachment" in this case prior to the close of discovery and at least three days prior to using such materials. CVS has objected to producing such impeachment materials, claiming—without support—that they are beyond the limits of proper discovery. Not true. "[T]he basic purpose of the federal rules, particularly those concerning discovery and disclosure, is to eliminate trial by ambush." *Djangmah v. Falcione*, No. 08 CIV. 4027 KPF, 2013 WL 6388364, at *4 (S.D.N.Y. Dec. 5, 2013). Accordingly, under Rule 26(b)(1), "a party legitimately may seek discovery of facts that relate to any of the six forms of impeachment" that "may be employed at trial." *Behler v. Hanlon*, 199 F.R.D. 553, 561 (D. Md. 2001).

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[5] Relator conditioned its offer on CVS providing it with sufficient information to allow him to make an informed decision as to which pharmacy locations to select. This includes the number of CVS specialty pharmacies that dispensed Gleevec, Tasigna, TOBI, or Podhaler, their names and locations, the identity of the five that had the highest volume of Gleevec, Tasigna, TOBI, or Podhaler refills, and the identity of the five that had the greatest number of individuals on an oncology or TOBI therapy team.

III. Conclusion

For the reasons stated, Relator respectfully asks the Court to order CVS to:

(1) substantially complete its production and disclose to Relator whether it intends to pursue a good faith defense by June 1, 2015;

(2) search for and produce documents beginning January 1, 2007;

(3) treat TOBI Podhaler as a "Covered Drug" for purposes of responding to his requests and not limit its TOBI Podhaler production to documents or information that concern exclusively those patients who switched from TOBI to TOBI Podhaler;

(4) identify its former Customer Service Representatives;

(5) produce documents concerning referrals of patients to CVS;

(6) produce documents related to remuneration other than those labeled as either a "rebate" or "discount";

(7) produce its advertisements for Customer Service Representative employment applications;

(8) produce its bonus policies; and

(9) produce any documents or materials it intends "to use or may use for impeachment" in this case prior to the close of discovery and at least three days prior to using such materials.

We are available to discuss this issue at the Court's convenience, and we greatly appreciate the Court's attention to this matter.

Respectfully,

Andres C. Healy